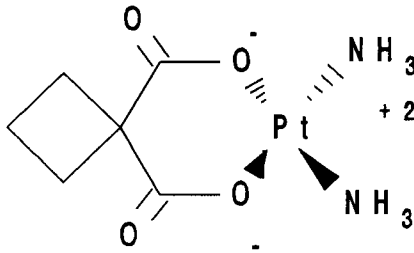


CARBOPLATIN

NSC - 241240



Chemical Name: Diammine[1,1-cyclobutanedicarboxylato-(2-)-O,O']platinum (II), (SP-4-2)-

Other Names: CBDCA, Paraplatin®, JM-8,
Carboplatin (USAN)

CAS Registry Number: 41575-94-4

Molecular Formula: C₆H₁₂N₂O₄Pt

M.W.: 371.3

How Supplied: For injection, 150 mg, vial: supplied as a white lyophilized powder with 150 mg of mannitol, USP, in a 20 mL amber vial.

Solution Preparation: 150 mg/vial: When constituted with 9.8 mL of Sterile Water for Injection, USP, each milliliter contains 15 mg of carboplatin and 15 mg of mannitol, USP, at pH 4.5 to 7.0.

Storage: Store the intact vials at room temperature.

Stability: The intact vials are stable for 5 years at room temperature (22-25 °C), and are stable for at least one year at elevated temperature (50 °C). Intact vials bear a three year expiration date.

When constituted as directed, the solution of carboplatin exhibits no decomposition for at least 24 hours at room temperature (22-25 °C).

Further dilution to concentrations of approximately 0.5 mg/mL and 2 mg/mL in 5% Dextrose Injection, USP, results in solutions exhibiting no decomposition for at least 24 hours at room temperature.

In a published study, at carboplatin concentrations of 0.1 and 1 mg/mL in 5% Dextrose Injection, USP, little or no decomposition occurred at 25 °C over the 6-hour study period. At 1 mg/mL in 5% Dextrose in 0.45% or 0.2% Sodium Chloride Injection, USP, little or no loss occurred in 6 hours and about 2% loss occurred in 24 hours at 25 °C. No difference was noted between glass and PVC containers (1).

However, dilution to a 1 mg/mL concentration in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose in 0.9% Sodium Chloride Injection, USP, resulted in about 5% decomposition in 24 hours at 25 °C (1). These solutions are not recommended for the dilution of carboplatin because of this increased decomposition and the possible formation of the more toxic cisplatin.

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous

Reference:

Cheung YW, Cradock JC, Vishnuvajjala BR, and Flora, KP: Stability of cisplatin, iproplatin, carboplatin, and tetraplatin in commonly used intravenous solutions, *Am J Hosp Pharm* 44:124-130, 1987.